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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/700,032  | 11/03/2003  | Hani Sabbah          | 1059.00096          | 3424             |
| 48924 7590 11/03/2008<br>KOHN & ASSOCIATES, PLLC<br>30500 NORTHWESTERN HWY, SUITE 410<br>FARMINGTON HILLS, MI 48334 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| AFREMOV, VERA   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1657  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 11/03/2008  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                          |                        |                     |  |
|--------------------------|------------------------|---------------------|--|
| <b>Interview Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                          | 10/700,032             | SABBAH ET AL.       |  |
|                          | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                          | JON WEBER              | 1657                |  |

All participants (applicant, applicant's representative, PTO personnel):

- (1) JON WEBER. (3) Laura Dellal.  
 (2) Kenneth Kohn. (4) \_\_\_\_\_.

Date of Interview: 28 October 2008.

Type: a) ☐ Telephonic b) ☐ Video Conference  
 c) ☒ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative)

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 2 and 15.

Identification of prior art discussed: Kornowski, McIntosh.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

|  |   |
|--|---|
|  | /JON P WEBER/<br>Supervisory Patent Examiner, Art Unit 1657 |
|--|---|

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The 112/2 rejections were discussed. It was agreed that applicants would clarify the cardiac functions in claim 15. It was agreed that the antecedent basis in claim 2 would be corrected. It was agreed that clarification if "intracoronary" and "directly to the heart" in claim 2 are different would be obtained. In the obviousness rejection options were explored to overcome the rejection of record. Two distinctions between the invention and Kornowski were identified: the hypoxic conditions, and the nature of the composition to be administered. It was agreed that the hypoxic conditions in Kornowski allow for and describe low levels of oxygen, 0.5-1% oxygen, whereas the instant conditions are anoxic at 95% nitrogen and 5% carbon dioxide. However, it was discussed that Kornowski indicate that the exact amount of hypoxia is not critical to the factors secreted by the stem cells into the medium as long as it is below 5%. Thus the same factors albeit at possibly different amounts are secreted and the conditioned medium will contain the same factors. The instant claims do not recite any particular amount of medium or factors to be administered, and even if they did a person of ordinary skill in the art could adjust such a result effective variable as amount and concentration. Hence, it was suggested that distinguishing from Kornowski (or McIntosh) on the basis of the hypoxic conditions would not be likely to overcome a prima facie case for obviousness. The composition to be administered in the instant claims would appear to be the conditioned medium in the absence of the stem cells that produced it. The current claim language is just ambiguous enough to be interpreted as open language and thereby encompass the subject matter disclosed in claim 15 of Kornowski. It was suggested that clearly closed language "a product consisting of the conditioned medium" would close the claim compared to Kornowski's claim 15m and overcome the antecedent problem as well. There remained the question of whether the passage in Kornowski at column 15, line 57-58 which recites "autologous bone marrow and/or bone marrow products are injected into the heart muscle" would allow the obviousness rejection to be maintained even with closed language. This latter question was not resolved. Both examiner and attorneys indicated that this would be studied carefully. Examiner Weber will discuss this final issue with Examiner Afremova who is examining this application.